IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Rheinfrank, et al.,	:	
	:	Case No. 1:13-cv-144
Plaintiffs,	:	
	:	Judge Susan J. Dlott
v.	:	
	:	Order Denying Plaintiffs' Motion for
Abbott Laboratories, Inc., et al.,	:	Relief from Order Pursuant to Rule 60
	:	Based Upon Fraud, Misrepresentation
Defendants.	:	and Misconduct; and Request for
	:	Sanctions Pursuant to 28 U.S.C. § 1927

This is a product liability case under Ohio law arising from Plaintiff Pamela Rheinfrank's ingestion of the antiepileptic drug, Depakote[1], during her pregnancy with her daughter, M.B.D. Currently pending before the Court is Plaintiffs' Motion for Relief from Order Pursuant to Rule 60 Based Upon Fraud, Misrepresentation and Misconduct; and Request for Sanctions Pursuant to 28 U.S.C. § 1927 (Doc. 259). The Court has reviewed the Motion, Defendants' Response in Opposition (Doc. 265), and Plaintiffs' Reply in Support of their Motion (Doc. 267). For the following reasons, Plaintiffs' Motion will be **DENIED**.

I. BACKGROUND

On August 10, 2015, the Court issued an Order Granting in Part and Denying in Part Defendants' Motion for Summary Judgment and Denying Plaintiffs' Motion for Partial Summary Judgment. *Rheinfrank v. Abbott Lab.*, Inc., No. 13-cv-144, --- F. Supp. 3d ---, 2015 WL 4743056 (S.D. Ohio Aug. 10, 2015). Plaintiffs challenge the Court's granting summary judgment for the Defendants on Plaintiffs' strict liability design defect claim in its Order.

[1] "Depakote" refers to Abbott's group of prescription drugs with the basic active ingredient valproic acid. Depakote is also sometimes referred to by the chemical names "valproic acid," "valproate," or "divalproex sodium." Depakote is an anti-epilepsy drug ("AED") that has been marketed by Abbott in the United States in some form since 1978.

Plaintiffs argue that they are entitled to relief from judgment pursuant to Fed. R. Civ. P. 60(b)(3), because Defendants misrepresented the record evidence applicable to their design defect claim, which influenced the Court's ruling. Plaintiffs also argue Defendants mistake the law on design defect. Plaintiffs contend they are entitled to sanctions pursuant to 28 U.S.C. § 1927 and the Court's inherent authority. In response, Defendants argue Plaintiffs have failed to identify admissible evidence in response to Abbott's argument that there was an absence of proof on an element of their design defect claim. Further, Defendants contend Plaintiffs have not met the demanding standard for reconsideration of a judgment under Rule 60(b)(3), and there are no proper grounds for sanctions.

II. STANDARDS GOVERNING MOTIONS FOR RECONSIDERATION

A. Rule 60(b)(3)

Plaintiffs moved the Court for relief from its judgment on their design defect claim under Fed. R. Civ. P 60(b), which states:

> (b) Grounds for Relief from a Final Judgment, Order, or Proceeding. On motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons:
> (1) mistake, inadvertence, surprise, or excusable neglect;
> (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b);
> (3) fraud (whether previously called intrinsic or extrinsic), misrepresentation, or misconduct by an opposing party;
> (4) the judgment is void;
> (5) the judgment has been satisfied, released or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or
> (6) any other reason that justifies relief.

Fed. R. Civ. P. 60(b). Plaintiffs assert that under Rule 60(b)(3), they must, as the moving party, demonstrate by clear and convincing evidence that one or more of the three types of misbehavior identified under Rule 60(b)(3) occurred. *Jordan v. Paccar, Inc.*, No. 95-3478, 97 F.3d 1452

(Table), 1996 WL 528950, at *8 (6th Cir. Sept. 17, 1996). Once demonstrated, "[the court's] abiding concern with the finality of judgments leads to the conclusion that the non-moving party should be permitted to demonstrate by clear and convincing evidence that the misbehavior which occurred had no prejudicial effect on the outcome of the litigation." *Id.* "If the non-moving party cannot make such a showing, however, then the moving party should be granted appropriate relief." *Id.*

The Defendants argue, and the Court agrees, that Plaintiffs move the Court for reconsideration under the wrong rule, as Rule 60 applies only to "final" orders, rendering it inapplicable to the court's ruling on summary judgment. Fed. R. Civ. P. 60; *see Payne v. The Courier-Journal,* 193 Fed. App'x 397, 400 (6th Cir. 2006) (affirming district court's denial of Rule 60(b) motion on the basis that it was not a proper basis for a challenge to a motion to transfer, which is not a final order); *McWhorter v. ELSEA, Inc.*, No. 2:00-cv-473, 2006 WL 3483964, at *1–2 (S.D. Ohio Nov. 30, 2006) ("an order of partial summary judgment is interlocutory in nature"); *see* 12 *Moore's Federal Practice* § 60.23 ("Rule 60(b) does not govern relief from interlocutory orders...."). Even the case cited by Plaintiffs in support of their motion, *Paccar*, emphasizes the overriding concern in regarding the finality of a judgment being challenged with respect to a Rule 60 motion. 97 F.3d 1452 (Table), 1996 WL 528950, at *8. On this basis alone, Plaintiffs' motion should be denied.

b. Rule 59(e)

However, the Court will consider the motion from the perspective of Rule 59(e) governing motions for reconsideration. "[D]istrict courts have inherent power to reconsider interlocutory orders and reopen any part of a case before entry of a final judgment." *Dunn v. Savage* (*In re Saffady*), 524 F.3d 799, 803 (6th Cir. 2008) (citing *Mallory v. Eyrich*, 922 F.2d

1273, 1282 (6th Cir. 1991)). This inherent power to vacate orders prior to entry of final judgment is recognized by Rule 59 of the Federal Rules of Civil Procedure, and is "distinct from the power explicitly granted by Rule 60 to reopen cases well after final judgment has been entered." *Id.*

Motions for reconsideration are treated as motions to amend a judgment pursuant to Rule 59(e) of the Federal Rules of Civil Procedure. There are three grounds for amending a judgment pursuant to Rule 59(e): "(1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at the time of trial; and (3) to correct a clear error of law or to prevent manifest injustice." *Berridge v. Heiser*, 993 F. Supp. 1136, 1146–47 (S.D. Ohio 1997); *see also GenCorp, Inc. v. American Int'l Underwriters*, 178 F.3d 804, 834 (6th Cir. 1999) (same). Resolution of a motion for reconsideration is within the discretion of the district court. *Cline v. City of Mansfield*, 745 F. Supp. 2d 773, 841 (N.D. Ohio 2010). However, motions for reconsideration are disfavored as explained by another court in the Southern District of Ohio:

> [A] "Rule 59(e) motion may not be used to re-litigate old matters, or to raise arguments or present evidence that could have been raised prior to the entry of judgement." *J.P. v. Taft,* No. C2–04–692, 2006 WL 689091, at *13 (S.D. Ohio Mar. 15, 2006) (quoting *Brown v. City of Syracuse,* No. 5:01–CV–1523, 2005 WL 2033492, at *1–2 (N.D.N.Y. Aug. 17, 2005)). Further, "[a] motion to alter or reconsider a judgment is an extraordinary remedy and should be granted sparingly because of the interest in finality and conservation of scarce judicial resources." *Vanguard Transp. Sys., Inc. v. Volvo Trucks N. Am., Inc.,* No. 2:04–CV–889, 2006 WL 3097189, at *2 (S.D. Ohio Oct. 30, 2006) (quoting *United States v. Limited, Inc.,* 179 F.R.D. 541, 547 (S.D. Ohio 1998) (internal citation omitted)). "If the movant simply regurgitates arguments previously presented or presents arguments which originally could have been argued, then the movant's proper recourse is an appeal to the circuit court.["] *Id.* (internal citation omitted).

Corl v. Citizens Bank, No. 2:08-CV-234, 2009 WL 650424, at *3 (S.D. Ohio March 10, 2009) (denying motion for reconsideration when the court already had addressed the plaintiff's "new"

argument and dismissed it). The Court will consider Plaintiffs' motion under Rule 59(e)(3).

III. ANALYSIS

A. Design Defect Claim

The Court will briefly review the elements of the statutory design defect claim contested here before delving into the parties' arguments. A product is defective in design if either of the following applies:

> If, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation as determined pursuant to division (B) of this section exceeded the benefits associated with that design or formulation as determined pursuant to division (C) of this section.
> (1) When it left the control of its manufacturer, the foreseeable risks associated with its design or formulation as determined pursuant to division (B) of this section exceeded the benefits associated with that design or formulation as determined pursuant to division (C) of this section;
> (2) It is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

Ohio Rev. Code § 2307.75(A) (2001) (amended 2004). "This statute offers two alternative approaches for demonstrating a design defect: a risk-benefit test in subsection (A)(1), and a consumer-expectations test in subsection (A)(2)"; thus, a jury may consider either or both theories of liability. *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 529 (6th Cir. 2012) (citing *Perkins v. Wilkinson Sword, Inc.*, 700 N.E.2d 1247, 1248 (1998)). In addition to meeting at least one of the two design-defect theories, Plaintiffs must also show there was no "practical and technical feasible alternative design that . . . that would have prevented the harm for which the claimant seeks to recover . . ." Ohio Rev. Code §2307.75(F); *Monroe v. Novartis Pharm. Corp.*, 29 F. Supp. 3d 1115, 1124 (S.D. Ohio 2014) ("Although this subsection does not state that it is a plaintiff's burden to prove an alternative design, the Sixth Circuit has so held." (citing *McGrath v. Gen. Motors Corp.*, 26 Fed. App'x 506, 510 (6th Cir. 2002)).

In its summary judgment ruling, the Court focused its analysis on whether Plaintiffs had come forward with evidence of an alternative design, noting, however, that Defendants also argued other bases for which they were entitled to summary judgment (in particular, that there was no evidence the risks outweighed the benefits and that the design defect claim was preempted.) *Rheinfrank*, 2015 WL 4743056, at *28, n2. The Court held:

> Defendants argue, and the Court agrees, that there is no evidentiary support for Plaintiffs' contention that there were alternative drugs that could have controlled Rheinfrank's grand mal tonic-clonic seizures as well as the Depakote/Phenobarbital combination that as prescribed for her for over twenty years, including by neurologists at the UC Neurology Clinic. None of Plaintiffs' experts have opined that Keppra, which Rheinfrank started taking in 2008, or any other AED, would have been a viable alternative for her in the period of time shortly before Rheinfrank became pregnant with M.B.D. Merely because some AEDs are considered less teratogenic than Depakote does not mean they would have been suitable for controlling Rheinfrank's seizures. Plaintiffs ask this Court to make an inferential leap by concluding that the fact that Rheinfrank now takes Keppra, a less teratogenic AED, and has been seizure free since, necessarily establishes that her taking Keppra, or another AED, would have controlled her seizures and prevented M.B.D.'s injuries. Absent expert testimony to support this proposition, the Court is unable to conclude Plaintiffs have met their burden to demonstrate an alternative design exists that would have prevented the harm for which they seek to recover. On this basis, summary judgment for the Defendants on this claim is appropriate. *See Monroe* 29 F. Supp. 3d at 1124.

Rheinfrank, 2015 WL 4743056, at *28.

Plaintiffs claim that the Court relied upon a material misrepresentation by the Defendants in granting summary judgment for the Defendants on its design defect claim. Specifically, Plaintiffs claim that Defendants' misrepresented the record by stating that "[n]one of Plaintiffs' experts have opined that Keppra (aka levetiracetam), which Rheinfrank started taking in 2008, or any other AED, would have been a viable alternative for her in the period of time shortly before Rheinfrank became pregnant with M.B.D." (Doc. 176 at PageID 23481.) Plaintiffs argue that contrarily, Defendants deposed Plaintiffs' experts on these precise issues, and, in particular, Dr. Privitera identified carbamazepine, phenytoin, lamotrigine, topirimate, levetiracetam, and

zonisamide as available drugs for treatment of tonic clonic seizures prior to 2003. (Privitera Dep., Doc. 109 at PageID 11678, 11681; Doc. 109-1 at PageID 11713–14.) Plaintiffs argue their experts cited numerous published articles comparing AEDs, and that these articles report many options as equivalent or superior to Depakote in terms of efficacy for treatment of tonic clonic seizures. Plaintiffs argue that in light of this evidence, Defendants' representation that Plaintiffs' experts provided no opinions on alternative treatment options was a blatant misrepresentation which influenced the Court's ruling granting summary judgment for the Defendants on Plaintiffs' design defect claim.

Defendants responded that they asserted multiple grounds that the design defect claim should fail in support of their motion for summary judgment and argues that if the Court considers Plaintiffs arguments in its motion for reconsideration, its other arguments asserted in its summary judgment motion should be considered. With respect to whether alternative designs existed – which ultimately was the basis upon which the Court ruled – Defendants argue that their argument was not that alternative AEDs were not available to treat tonic-clonic seizure, but that there was no evidence that any of the other AEDs would have controlled Plaintiff Rheinfrank's seizures as well as Depakote. Defendants contend that the Court reached the correct conclusion in granting summary judgment on the design defect claim on that basis.

In their Reply brief, Plaintiffs contend the Defendants argued and the Court adopted too narrow a construction of what a Plaintiff must show in demonstrating an alternative design exists. As noted above, the Court emphasized whether there was evidence that an alternative design existed that would have prevented the harm for which Plaintiff sought to recover. Plaintiffs argue this need only be demonstrated for the class of Plaintiffs (in this case, tonic clonic seizure patients), as opposed to Plaintiff specifically, as it would be nearly impossible to

go back in time to demonstrate that alternative drugs would have controlled Plaintiffs' seizures and prevented harm to M.B.D.

In support of their argument, Plaintiffs rely upon *Keffer v. Wyeth,* 791 F. Supp. 2d 539, 548–550 (S.D. W.Va. 2011) (rejecting argument that the plaintiff's alternative design theory failed because plaintiff had not shown that the alternative design would have avoided her specific injury, as opposed to decreasing the risk of harm generally); *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 901 (E.D. Va. 2010) (rejecting argument that plaintiff's experts discussing the diminishing risk of cancer generally from the alternative design were insufficient because they needed to discuss the diminished risk to plaintiff specifically). Upon reconsideration, the Court is persuaded that it misconstrued Plaintiffs' burden in coming forward with evidence of an alternative design.

B. Preemption

However, even if the Court did misconstrue Plaintiffs' burden in coming forward with evidence of an alternative design, there is no error in outcome. As noted above, the Court did not fully consider the Defendants' preemption argument in ruling on the design defect claim, but must do so now to fully adjudicate the Plaintiffs' motion. In support of their design defect claim, Plaintiffs argue that it would be a viable alternative design for Abbott to manufacture other drugs as opposed to Depakote, such as Keppra.

In their motion for summary judgment, Defendants argued that Plaintiffs' suggestion that Abbot could tweak the Depakote molecule to make it safer is not supported by expert testimony and is preempted under *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013). The Supreme Court in *Bartlett* held that "warning-based design-defect cause[s] of action [are] pre-empted with respect to FDA-approved drugs sold in interstate commerce." *Id.* at 2477. That is,

"state-law design defect claims . . . that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Id.* at 2479. Creating an alternative design would require changing the composition of an FDA-approved drug, which is prohibited by federal law. *Id.* at 2479.

Although Plaintiffs argue this holding is limited to generic drugs and does not extend to brand drugs, the language of *Bartlett* is not so restrictive. The Court adopts the reasoning of the Northern District of Ohio in *Yates v. Ortho-McNeil Pharmaceutical Inc.*:

> Although [plaintiff's] attorneys assert that the preemption is applicable to only generic drugs, the language in *Bartlett* and *Amos* is not so restrictive. The Supreme Court specifically stated that "[o]nce a drug – *whether generic or brand-name* – is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application.' 21 C.F.R. § 314.70(b)(2)(i)" *Bartlett*, 133 S. Ct. at 2471 (emphasis added). The Court held that "state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Id.* at 2479. This language establishes that the Supreme Court did not limit its holding in *Bartlett* to generic drugs, although the drug in question was generic. *Id.* at 2471, 2480; see also *Amos [v. Biogen Indec Inc.]*, 28 F. Supp. 3d [164,] at 167 [(W.D.N.Y. 2014)] (drug in question was not generic).

76 F. Supp. 3d 680, 686 (N.D. Ohio Jan. 5, 2015).

Furthermore, Plaintiffs' argument that there is an exception under footnote 4 of the *Bartlett* ruling is unavailing, because Plaintiffs did not plead misbranding in their Complaint. *See In re Darvocet, Darvon, and Propoxyphene Prod. Liab. Litig. v. Teva Pharm., USA, Inc.*, 756 F.3d 917, 928–29 (6th Cir. 2014) (acknowledging confusion over footnote 4 of the *Bartlett* ruling and whether a state parallel misbranding claim escapes preemption, because plaintiffs failed to plead such a claim).

IV. SANCTIONS

The Court does not find that Defendants' conduct is grounds for sanctions under either 28 U.S.C. § 1927 or the Court's inherent powers.

V. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Relief from Order Pursuant to Rule 60 Based Upon Fraud, Misrepresentation and Misconduct; and Request for Sanctions Pursuant to 28 U.S.C. § 1927 (Doc. 259) is **DENIED**.

IT IS SO ORDERED.

Judge Susan J. Dlott
United States District Court